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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,137	07/25/2000	Pramod K. Srivastava	8449-123-999	8478

20583 7590 03/19/2004

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/625,137	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-23,64 and 67-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14, 17-23, 64, and 67-112* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/2003 has been entered.

2. Claims 15-16, 24-63, and 65-66 are canceled without prejudice or disclaimer, claims 77-112 are newly added.

3. Claims 1-14, 17-23, 64, and 67-112 are pending.

4. Upon review and reconsideration and in view of newly submitted claims, the instant application is deemed to contain multiple and or distinct inventions.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2,3,4,5,6,7,8,9,10,14,17,19,20,64,67,77, and 78 are drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process comprising contacting a test compound with **α2m receptor** and a heat shock protein, binding fragment thereof, or a purified HSP-peptide complex, and measuring the level of HSP binding activity,

HSP uptake, or HSP-mediated antigen representation activity, wherein the compound is specifically drawn to an antagonist and the α2M receptor is purified, classified in class 436, subclass 500. ***If applicant elects this group for prosecution on the merits, applicant must elect a single compound for examination from claims 3-10. This election should not be construed as a election of species – see paragraph 6 below.***

II. Claims 1,3,4,5,6,7,8,9,10,11,14,19,20,64,67,77, and 78 are drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process comprising contacting a test compound with **α2M receptor** and a heat shock protein, binding fragment thereof, or a purified HSP-peptide complex, and measuring the level of HSP binding activity, HSP uptake, or HSP-mediated antigen representation activity, wherein the compound is specifically drawn to an agonist and the α2M receptor is purified, classified in class 436, subclass 500. ***If applicant elects this group for prosecution on the merits, applicant must elect a single compound for examination from claims 3-10. This election should not be construed as a election of species – see paragraph 6 below.***

III. Claims 1,2,3,4,5,6,7,8,9,10,12,14,19,20,64,67,77,and 78, are drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process **affecting** diabetes or other autoimmune disorders, a disease or disorder involving disruption of antigen presentation or endocytosis, a disease or disorder involving cytokine clearance or inflammation, a proliferative disorder, a viral disorder or other infectious

disease, hypercholesterolemia, Alzheimer's disease, or osteoporosis comprising contacting a test compound with α2m receptor and a heat shock protein, binding fragment thereof, or a purified HSP-peptide complex, and measuring the level of HSP binding activity, HSP uptake, or HSP-mediated antigen representation activity, wherein the compound is specifically drawn to an antagonist and the α2M receptor is purified, classified in class 514, subclass 2. ***If applicant elects this group for prosecution on the merits, applicant must elect a single compound for examination from claims 3-10. This election should not be construed as a election of species – see paragraph 6 below.***

IV. Claims 1,3,4,5,6,7,8,9,10,11,12,14,19,20,64,67,77, and 78, are drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process **affecting** diabetes or other autoimmune disorders, a disease or disorder involving disruption of antigen presentation or endocytosis, a disease or disorder involving cytokine clearance or inflammation, a proliferative disorder, a viral disorder or other infectious disease, hypercholesterolemia, Alzheimer's disease, or osteoporosis comprising contacting a test compound with α2m receptor and a heat shock protein, binding fragment thereof, or a purified HSP-peptide complex; and measuring the level of HSP binding activity, HSP uptake, or HSP-mediated antigen representation activity, wherein the compound is specifically drawn to an agonist and the α2M receptor is purified, classified in class 514, subclass 2. ***If applicant elects this group for prosecution on the***

merits, applicant must elect a single compound for examination from claims 3-10. This election should not be construed as a election of species – see paragraph 6 below.

V. Claims 13,14,17,18,21,22,23,76,77, and 78, are drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process comprising contacting a test compound with a **cell expressing an α2M receptor**, and a purified HSP or fragment thereof, or a purified HSP-peptide complex; and measuring the level of HSP binding activity, HSP uptake, or HSP-mediated antigen representation activity, classified in class 435, subclass 7.1.

VI. Claim 68, drawn to a method of identifying a compound that modulates an HSP-α2M receptor mediated process comprising contacting a test compound with an **α2M expressing cell** and a purified HSP, or fragment thereof, or a purified HSP-peptide complex; and measuring the level of α2M receptor activity by a signal transduction activity assay, heat shock protein uptake assay, chemotaxis assay, or calcium ion concentration assay, classified in class 435, subclass 7.1.

VII. Claims 69 and 79, are drawn to a method of screening a plurality of molecules for one or more molecules having the ability to modulate, directly, or indirectly, the antigen presentation of α 2M receptor-expressing cell comprising contacting said plurality of molecules with said α 2M receptor-expressing cells and a purified complex of a heat shock protein

and the antigenic peptide; measuring antigen presentation by said α 2Mreceptor-expressing cells in the presence of said plurality of molecules; and comparing antigen presentation activity by said α 2M receptor-expressing cells in the presence of said plurality of molecules with antigen presentation activity by said α 2M receptor-expressing cells in the absence of said plurality of molecules, classified in class 435, subclass 7.93.

VIII. Claims 70,75, and 79, are drawn to a method of screening an **antibody specific to HSP** for the ability to modulate, directly, or indirectly, the antigen presentation of α2M receptor-expressing cell comprising contacting said antibody with α2M receptor-expressing cells and a purified complex of a heat shock protein and the antigenic peptide; measuring antigen presentation by said α2M receptor-expressing cells in the presence of said antibody; and comparing antigen presentation activity by said α2M receptor-expressing cells in the presence of the antibody with antigen presentation activity by said α2M receptor-expressing cells in the absence of the antibody, wherein the antibody is specific for HSP, classified in class 435, subclass 7.1.

IX. Claims 70,75, and 79, are drawn to a method of screening an **antibody specific to α2M** for the ability to modulate, directly, or indirectly, the antigen presentation of α2M receptor-expressing cell comprising contacting said antibody with α2M receptor-expressing cells and a purified

complex of a heat shock protein and the antigenic peptide; measuring antigen presentation by said α2M receptor-expressing cells in the presence of said antibody; and comparing antigen presentation activity by said α2M receptor-expressing cells in the presence of the, classified in class 435, subclass 7.1.

X. Claims 71,75, and 79, are drawn to a method for screening **a molecule** for the ability to modulate, directly or indirectly, the antigen presentation activity of α 2M receptor-expressing cells, comprising contacting the molecule with purified α2M receptor-expressing cells and a purified complex of a heat shock protein and an antigenic peptide; measuring antigen presentation by the α2M receptor-expressing cells in the presence of the molecule; and comparing antigen presentation activity by the α2M-expressing cells in the presence of the molecule with antigen presentation activity by the α2M receptor-expressing cells in the absence of the molecule, classified in class 435, subclass 7.2.

XI. Claims 72,75, and 79, are drawn to a method for screening a **plurality of molecules** for one or more molecules having the ability to modulate, directly or indirectly, the ability of an α2M receptor-expressing cell to activate cytotoxic T cells in vitro comprising contacting said plurality of molecules with cells expressing α2M receptor, a purified complex of a heat shock protein and a peptide, and cytotoxic T cells, under conditions conducive to the activation of cytotoxic T cells; comparing the activation in

vitro of said T cells with the activation in vitro of T cells in the absence of said plurality of molecules, classified in class 435, subclass 7.93.

XII. Claims 73, and 79, are drawn to a method for screening an **antibody specific to a HSP** for the ability to modulate, directly or indirectly, the ability of an α2M receptor-expressing cell to stimulate the activation of activate cytotoxic T cells in vitro comprising contacting the antibody with cells expressing α2M receptor, a purified complex of a heat shock protein and a peptide, and cytotoxic T cells, under conditions conducive to the activation of cytotoxic T cells; comparing the activation in vitro of said T cells with the activation in vitro of T cells in the absence of said plurality of molecules, wherein the antibody is specific for HSP, classified in class 435, subclass 7.1.

XIII. Claims 73 and 79, are drawn to a method for screening an **antibody specific to an α 2M receptor** for the ability to modulate, directly or indirectly, the ability of an α2M receptor-expressing cell to stimulate the activation of activate cytotoxic T cells in vitro comprising contacting the antibody with cells expressing α2M receptor, a purified complex of a heat shock protein and a peptide, and cytotoxic T cells, under conditions conducive to the activation of cytotoxic T cells; comparing the activation in vitro of said T cells with the activation in vitro of T cells in the absence of said plurality of molecules, wherein the antibody is specific for α 2M receptor, classified in class 435, subclass 7.1.

XIV. Claims 74 and 79, are drawn to a method for screening a **molecule** for the ability to modulate, directly or indirectly, the ability of an α 2M receptor-expressing cell to stimulate the activation of activate cytotoxic T cells in vitro comprising contacting said molecule with a purified cells expressing α 2M receptor, a purified complex of a heat shock protein and a peptide, and cytotoxic T cells, under conditions conducive to the activation of cytotoxic T cells; comparing the activation in vitro of said T cells with the activation in vitro of T cells in the absence of said plurality of molecules, classified in class 435, subclass 7.24.

XV. Claims 80,81,83,85,86,87,88, 89,90,91,92,94,95,96,104,105,106,107, 108,109,110,111, and 112, are drawn to a method for identifying a compound that modulates an HSP-α2M receptor-mediated process, comprising contacting a test compound with **a ligand-binding fragment of an α2M receptor**, and a purified heat shock protein, or a binding fragment thereof, or a purified HSP-peptide complex; and measuring the level of HSP binding activity, HSP uptake activity, or HSP-mediated antigen representation activity, classified in class 436, subclass 500. ***If applicant elects this group for prosecution on the merits, applicant must elect (1) a single compound for examination from claims 85-92, and (2) a single SEQ ID Number from claim 112 for examination. This election should not be construed as a election of species – see paragraph 6 below.***

XVI. Claims 93,94,95,96,97,98,99,100,101,102,103,104,105,106,107,108, 109,110, 111, and 112, are drawn to a method for identifying a compound

that modulates an HSP-α2M receptor-mediated process comprising contacting a test compound with **a cell expressing a ligand-binding fragment of an α2M receptor** and a purified heat shock protein, or fragment thereof, or a purified HSP-peptide complex; and measuring the level of HSP binding activity, HSP uptake activity, or HSP-mediated antigen representation activity in the cell, classified in class 436, subclass 500. ***If applicant elects this group for prosecution on the merits, applicant must elect a single SEQ ID Number from claim 112 for examination. This election should not be construed as a election of species – see paragraph 6 below.***

The inventions are distinct, each from the other because of the following reasons:

6. Inventions of groups I-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated in that the methods of the different groups require the use of different components all of which have different structures and functions; have different purposes, such as for the screening of different types of modulators; and have different outcomes of which are intended to derive different types of activation or modulation.

7. Because these inventions are distinct for the reasons given above and the search required for the different groups is not required one for the other, restriction for examination purposes as indicated is proper. In this case, the different methods of screening requires searching in different databases which are different from one another and a search in these different databases are considered burdensome.

8. Upon election of Groups I,II,III, IV, XV, or XVI, applicants are additionally required to elect a single compound and or sequence identified by a specific sequence identification number, as indicated above as they apply to group(s). The recited compounds and sequences have different structures one from other and the search for the compounds and or sequences would be unduly burdensome. This requirement is not to be construed as a requirement for an election of species, since each of the compounds and sequence(s) recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

9. Claim 12 is generic to a plurality of disclosed patentably distinct species comprising different types of diseases or disorders. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
March 16, 2004

GARY NICKOL
PRIMARY EXAMINER